PATENT

Attorney Docket No.: 37921-2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re:	Patent application of Robert Norman Rice et al.	:	
		:	Group Art Unit:
Serial No.:	not yet assigned	:	not yet assigned
Filed:	herewith	:	Examiner: not yet assigned
For:	A METHOD AND KIT	:	

Petition To Make Special Under 37 C.F.R 1.102(d)

Box New Patent Application
Commissioner for Patents
Washington, DC 20231

Sir:

This is a petition under 37 C.F.R. 1.012(d) to accord "special" status to the above-referenced patent application. A check in the amount of **$130** is submitted herewith, to satisfy the petition fee set forth in 37 C.F.R. 1.17(h). If additional fees are due, please charge Deposit Account No. 50-0573. This paper is submitted in duplicate.

For the reasons set forth below, Applicants request that examination of the above-referenced application be accelerated.

CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10

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Therese McKinley
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Grounds for According "Special" Status

The present invention relates:

- to the diagnosis, treatment and prevention of cancer and HIV/AIDS (MPEP 708.02(X)); and
- to countering terrorism (MPEP 708.02(XI)).

Statement Explaining How the Invention Contributes to the Diagnosis, Treatment and Prevention of Cancer and HIV/AIDS

The U.S. Patent and Trademark Office has long recognized the importance of promptly examining and disclosing advances made in the fields of cancer and AIDS research. The above-referenced application discloses and claims subject matter relevant to the diagnosis, treatment and prevention of both conditions.

The present invention involves the characterization of gene expression status in a cell by monitoring transcription with the a modified nuclear run-on assay. The assay of the invention measures RNA transcribed *in vitro* from preparations of cellular or viral nucleic acid or organelles by measuring the rate of product accumulation. A "fingerprint" or pattern of genetic activity in a cell is thus provided. The patterns obtained in response to different internal or external stimuli, or those resulting from different physiological or developmental states, can be obtained and evaluated. See pg. 1, ln. 25 to pg. 2, ln. 20 and pg. 4, lns. 17-28 of the specification.

For example, potential anti-cancer agents can be screened for their effect on the expression of normal and oncogenic genes in tumor cells. The knowledge gained from such studies has clear implications for identifying and developing new cancer therapeutics. Likewise, changes in gene expression in response to specific oncogenic stimuli can be characterized, leading to a better understanding of the molecular mechanisms of carcinogenesis. The present invention thus is specifically relates to the diagnosis, treatment and prevention of cancer.

The relevance of the present invention to the treatment, diagnosis and prevention of cancer was shown in certain of the working examples, in which cultured mammalian cells were transfected with various transgenes. The methods of the invention were used to detect

various mRNAs, including those of the transgene and the endogenous gene from which the transgene was derived. See pg. 30, ln. 26 to pg. 31, ln. 7 of the specification.

Examples 4 and 5, respectively, show the transfection of murine melanoma cells and human melanoma and breast cancer cells for use in subsequent gene expression assays according to the invention. Example 19 shows gene expression profiles for transfected and untransfected murine and human cancer cells. In particular, the relative transcription level of endogenous (Figure 5a) and exogenous (Figure 6b) HER2, an oncogene, was determined for the human breast cancer cells.

The present methods can also be used to monitor gene expression in cells infected with a pathogenic virus, such as the human immunodeficiency virus (HIV) which causes AIDS. See pg. 12 ln. 26 of the specification. In addition to evaluating changes in host and virus gene expression throughout the stages of HIV infection, potential antiviral agents can be evaluated for their ability to suppress HIV gene transcription in infected host cells. The present invention thus specifically contemplates applying the present methods toward the diagnosis, prevention and treatment of HIV infection and AIDS.

Statement Explaining How the Invention Contributes to Counter-Terrorism

In the months following the events of September 11, Americans were deliberately exposed to anthrax bacteria in a series of now-infamous acts of bioterrorism. The widespread disruption of private and government functions, and the deaths and sickness caused by these bioterroristic attacks, spotlighted the need for a concerted defense against this new threat.

A deeper understanding of bioterror pathogens such as the anthrax bacterium, *Bacillus anthracis*, is an essential part of an effective anti-bioterror campaign. For example, evaluation of *Bacillus anthracis* gene expression patterns, and how these patterns change in response to various stimuli, is important for developing more effective anthraxicides. A similar evaluation of other bioterror pathogens would also greatly benefit America's counter-terrorism efforts.

The present invention specifically contemplates the determination of gene expression patterns in prokaryotic cells, and is thus well-suited to this task. See pg. 11 ln. 22 of the specification. Bacillus spp., in particular *Bacillus anthracis*, are specifically identified as

organisms which can be evaluated and studied by the present methods. See pg. 12, ln. 2 and pg. 12, lns. 10-11 of the specification.

Other pathogens which may be used as bioterror weapons are also specifically identified in the specification; for example, the organisms which cause Legionnaire's Disease (*Legionella pneumophila*), meningitis (*Neisseria meningitidis*; *Hemophilus influenzae*), whooping cough (*Bordetella pertussis*), typhoid (*Salmonella typhi*), dysentery (*Shigella dysenteriae*), pneumonia (*Klebsiella pneumoniae*; *Mycoplasma pneumoniae*), bubonic plaque (*Yersinia pestis*), cholera (*Vibrio cholerae*), typhus (*Rickettsia rickettsii*), and diphtheria (*Corynebacterium diphtheriae*). See pg. 12, lns. 5-14 of the specification.

Specifically, using the present methods to elucidate these pathogens' gene expression patterns can help identify new molecular targets for antibacterial drug research. More immediately, new drugs can be identified by screening compounds for bactericidal or bacteristatic properties against *Bacillus anthracis* and the other pathogens listed above. Thus, the present invention directly contributes to counter-terrorism efforts.

Conclusion

The present invention concerns molecular biology techniques which have relevance to the diagnosis, treatment and prevention of cancer and HIV/AIDS, as well as the recent and necessary efforts in countering bio-terrorism. There is recognized importance in the prompt examination and disclosure of such inventions. Applicants therefore request that the Commissioner grant this petition, and designate the above-referenced application as "special" and subject to accelerated prosecution.

Respectfully submitted,

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BY _____

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